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EXAMINER	
PORTER, RACHEL L	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/560,597	MCALINDON ET AL.	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/25/03 & 4/30/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-18 and 20-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-18 and 20-38* is/are rejected.

7)☐ Claim(s) ~~37-38~~ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 7/25/03 & 4/30/04. Claims 1-14, 16-18, and 20-38 are pending. Claims 15 and 19 have been canceled.

Claim Objections

2. Claims 37-38 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). (For example claim 38 should be rewritten to refer to any one of claims the listed claims)

Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-14, 16-18, 20-25, and 28-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al (5,991,731) in view of Hopp (Hopp, David I, "Three

topics integral to the use of the Internet for clinical trials: Connectivity, communication, and security," Drug Information Journal, Oct-Dec, 1998).

(A) As per claim 1, Colon teaches a method of conducting a clinical trial of a test substance over the internet from a primary site, comprising the following steps:

assigning at the primary sight, a unique identifier and a unique log-in password to at least one clinical trial user located at a remote internet site distant from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site (Colon; col. 4, line 54-col. 5, line 24 and col. 7, lines 55–65);

accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site (Colon; col. 2, lines 58-63, figure 1, figure 6, and col. 7, lines 8-15) ;

providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section that, when completed by a participant using the test substance, provides information from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form (Colon; col. 7, lines 8-18 and figure 6; it is respectfully submitted that "question and answer selection" is a known form of "inputting patient data & events"); and

compiling data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial (Colon; col. 7, line 46-col. 8, line 5).

Colon fails to expressly teach providing to the clinical trial user, responsive to the receipt by the primary site of the unique identifier and the unique log-in password, instructions on using the test substance and also fails to expressly teach the clinical trial user as a clinical trial participant. However, this feature is old and well known in the art, as evidenced by Hopp's teachings with regards to this limitation. In particular, Hopp teaches the use of the Internet for clinical trials and teaches documents, such as contracts, informed consent forms, and study procedure manuals, shared with clinical trial participants for viewing and printing (Hopp; page 4, paragraphs 1-2; it is respectfully submitted that "instruction on using the test substance" is met by "study procedure manuals.") Furthermore, Hopp also teaches that a clinical trial participant's access to the system is confidential and controlled (Hopp; page 3, paragraphs 7-11; it is respectfully submitted, that it is well-known for a confidential and controlled access to a system to be based on a unique user identifier and password as shown above by Colon and incorporated herein). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Colon with Hopp's teaching with regards to this limitation, with the motivation of making information available in a more timely way to clinical trial participants (Hopp; page 3, paragraph 1).

As per claim 2, Colon teaches obtaining informed consent from the participant to participate in the clinical trial (Colon; col. 6, lines 53-66; the examiner interprets the "confirming of prescription" as a form of "obtaining informed consent.")

As per claim 3, Colon teaches wherein obtaining the participant's informed consent comprises sending a blank consent form from the primary site to the remote site, and receiving at the primary site from the remote site, a completed consent form from the participant to participate in the clinical trial (Colon; col. 6, lines 53-66; the examiner interprets the "initial suggested drug prescription" as a form of "blank consent form" and interprets the "results of physician's titration" as a form of "completed consent form.")

As per claim 4, Colon teaches:

causing a consent form to appear at the remote site (Colon; col. 6, lines 53-66; the examiner interprets the "initial suggested drug prescription" as a form of "consent form"), said consent form having information about the clinical trial (Colon; col. 6, lines 53-66; the examiner interprets the "prescription" as the "information about the clinical trial"), a portion allowing consent to be given to participate in the clinical trial (Colon; col. 6, lines 53-66; the examiner interprets the "confirm or adjust the prescription" as "allowing consent to be given to participate.")

Colon fails to expressly teach providing for authentication of the consent form.

However, this feature is old and well known in the art, as evidenced by Hopp's teachings with regards to this limitation. In particular, Hopp teaches the use of the Internet for clinical trials and identifying and individual or computer to ensure that he/it is a member of a specific set via authentication (Hopp; page 4, paragraph 7). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Colon with Hopp's teaching with regards to this limitation, with the motivation of ensuring identity of the participant, thereby maintaining the value of the information (Hopp; page 1, paragraph 4).

The combined system of Colon and Hopp collectively fail to expressly teach a portion of the consent form allowing consent to be given to release of the participant's medical information to at least one investigator conducting the clinical trial. However, since Colon does teach the restricting of access to study investigators (Colon; col. 7, lines 46-54) and since participant medical information is personal information, it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Colon and Hopp to obtain consent from participants for the release of medical information, with the motivation of obtaining authorization for enabling access to participant's private information to study investigators if desired.

As per claim 5, Colon teaches wherein a computer server at the primary site

causes the consent form to appear at the remote site computer in response to the primary site receiving from the remote-site, either a request for the consent form or a completed screening questionnaire, said questionnaire having portions for receiving information for use in making a determination of whether an individual upon whose behalf the questionnaire is answered, is eligible to be a participant in the clinical trial (Colon; col. 6, lines 22-55;)

Claim 6 differs from the features of claim 4 by reciting "wherein obtaining the participant's informed consent comprises a hardcopy consent form to the participant for completion and return to at least one investigator conducting the clinical trial." Colon does teach a "hardcopy consent form" signed by the participant (Colon; col. 6, line 66-col. 7), but the combined system of Colon and Hopp collectively fail to expressly teach the "hardcopy consent form" is returned to at least one investigator conducting the clinical trial. It is respectfully submitted, that since Colon does teach a "hardcopy consent form" and it is in the interest of a study investigator to verify and maintain a copy of the consent form in order to determine the accuracy and reliability of study results, it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Colon and Hopp to return the "hardcopy consent form" to one investigator conducting the clinical trial, with the motivation of enabling the investigator to verify and keep a copy of the consent form for recording purposes. The remaining features of claim 6 repeat features of claim 4

and are therefore rejected for the same reasons given above in the rejection of claim 4 and incorporated herein.

As per claim 7, Colon teaches screening potential candidates over the internet for eligibility to participate in the clinical trial, the screening comprising:

- maintaining, at the primary site, a website that is accessible from remote sites via the internet (Colon; col. 2, lines 58-67)

- causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site, of a request from the remote site to display the screening questionnaire, wherein the questionnaire has portions for receiving a candidate's information that enables a determination of whether a candidate is eligible to be a participant in the clinical trial (Colon; col. 6, lines 22-30);

- receiving the completed questionnaire at the primary site via the internet (col. 6, lines 29-30); and

- reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria (Colon; col. 6, lines 39-50).

Colon fails to expressly teach that the website provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial. However, this feature is old and well known in the art, as evidenced by Hopp's teachings with regards to this limitation. In particular, Hopp teaches the use of the Internet for clinical trials and teaches documents, such as contracts, informed consent forms, and study

procedure manuals, shared with participants for viewing and printing (Hopp; page 3, paragraphs 1-2; it is respectfully submitted that "information about the clinical trial" and "eligibility criteria" is met buy "study procedure manuals.") It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Colon with Hopp's teaching with regards to this limitation, with the motivation of making information available in a more timely way (Hopp; page 3, paragraph 1).

Claim 8 differs from the features of claims 1, 2, 5, and 7 by reciting "after receipt of the candidate's informed consent by at least one investigator, causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity and eligibility of the candidate to participate." Colon teaches the information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate (Colon; col. 6, line 39-col. 7, line 7). The combined system of Colon and Hopp collectively fail to expressly teach that the "information transfer" occurs after the receipt of the candidate's informed consent by at least one investigator. However, as shown above in rejection of claim 6, it is in the interest of a study investigator to verify and maintain a copy of the consent form in order to determine the accuracy and reliability of study results, as such it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Colon and Hopp to perform "information transfer" after the receipt of the candidate's informed

consent by at least one investigator, with the motivation of enabling the investigator to verify and keep a copy of the consent form for recording purposes prior to informing the participant of their status. The remaining features of claim 8 repeat features of claims 1, 2, 5, and 7 and are therefore rejected for the same reasons given above in the rejection of claims 1, 2, 5, and 7 and incorporated herein.

Claim 9 repeats features of claim 8 and is therefore rejected for the same reasons given above in the rejection of claim 8 and incorporated herein.

As per claim 10, Colon teaches wherein the confirming is accomplished by performing at least one step selected from the group consisting of: interviewing the participant by telephone or in person; reviewing at least one medical record of the participant; interviewing a health care professional who has provided health care to the participant; and reviewing at least one communication from the health care professional to the at least one investigator regarding the health status of the participant (Colon; col. 6, lines 22-50; it is respectfully submitted, that since the "attending physician" reports the "medical conditions" of the participant, the system of Colon does perform the "confirming" by "interviewing a healthcare professional who has provided health care to the participant.")

As per claim 11, Colon teaches wherein the eligibility of the participant to

participate in the clinical trial is determined by comparing the participant's answers to the questionnaire with a reference standard comprising conventionally accepted indications of a medical condition for which the test substance's effectiveness in treating is being tested (Colon; col. 6, lines 39-43; the examiner interprets the "accepted indications of a medical condition for which the test substance's effectiveness in treating is being tested " as a form of "eligibility parameters of the study.")

As per claim 12, Colon teaches causing the delivery of the test substance to the participant prior to compiling data regarding the at least one effect (Colon; col. 7, lines 2-7). However, the combined system of Colon and Hopp fail to expressly teach that the "delivery of the test substance" occurs under the authority of the investigator. However, since the investigator is interested in ensuring that the correct test substance is delivered to the participant so as to maintain the integrity and reliability of the study, it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Colon and Hopp to perform the "delivery of the test substance" under the authority of the investigator, with the motivation of ensuring the correct test substance is delivered.

As per claims 13-14, Colon teaches collecting and storing at a secure site, which is the primary site, accessible by the at least one investigator and by the participant, information from at least one member of the group consisting of: at least

one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator (Colon; col. 7, lines 46-61).

As per claim 16, Colon teaches monitoring at least one effect of the test substance on the participant by reviewing a plurality of evaluation forms each completed and returned by the participant to at least one investigator, wherein each of the multiple evaluation forms is provided electronically to the participant at predetermined different times after the participant has commenced using the test substance (Colon; col. 7, line 8-col. 8, line 10)

As per claim 17, Colon teaches multiple participants in the clinical trial (Colon; col. 5, lines 25-35; it is respectfully submitted, that since Colon teaches multiple rows for each patient in study, Colon does teach multiple participants in the clinical trial).

As per claim 18, Colon teaches assigning to the participant, a unique identifier and a unique log-in password for accessing protected information from the primary site (Colon; col. 5, lines 25-35 and col. 6, lines 15-21; it is respectfully submitted, that since each participant is stored separately in the database at the server, each participant does have a "unique identifier." It is also respectfully submitted, that since the "attending physician" enters the participant data for the participant in the system of Colon, "unique log-in password for accessing protected information from the primary

site" is met by "physician authorization levels.") Colon teaches monitoring at least one effect of the test substance on the participant by reviewing a plurality of evaluation forms each completed and returned by the participant to at least one investigator, wherein each of the multiple evaluation forms is provided electronically to the participant at predetermined different times after the participant has commenced using the test substance (Colon; col. 7, line 8-col. 8, line 10)

As per claims 20-22, Colon teaches providing encryption for information transmitted between the primary site and the remote site via the internet (Colon; col. 6, lines 34-38).

As per claim 23, Colon teaches the determination of the at least one effect comprises comparing answers from at least one evaluation form completed by the participant after having used the test substance, with answers from at least one evaluation form completed by the participant prior to using the test substance (Colon; col. 7, lines 8-45).

As per claims 24 and 25, Colon teaches determining, from the data compiled from received and completed evaluation forms from multiple participants, whether the test substance has clinical efficacy in treating a predetermined medical condition (Colon; col. 7, lines 8-45).

As per claim 28, the combined system of Colon and Hopp is implemented on a computer (Colon; figure 1). As such, Colon and Hopp implicitly include computer elements such as a programmed computer readable medium.

System claim 29 repeats the subject matter of method claim 1 as a set of apparatus elements rather than a series of steps. As the underlying processes of claim 1 has been shown to be fully disclosed by the collective teachings of Colon and Hopp in the above rejections of claim 1, it is readily apparent that the system disclosed collectively by Colon and Hopp includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for method claim 1, and incorporated herein.

System claims 29-36 repeat the subject matter of method claims 1, 4, 4, 7, 7, 11, 8, 8, and 20, respectively, as a set of apparatus elements rather than a series of steps. As the underlying processes of claims 1, 4, 7, 11, 8, 13, and 20 have been shown to be fully disclosed by the collective teachings of Colon and Hopp in the above rejections of claims 1, 4, 7, 11, 8, 13, and 20, it is readily apparent that the system disclosed collectively by Colon and Hopp includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for method claims 1, 4, 7, 11, 8, 13, and 20, and incorporated herein.

5. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al (5,991,731) and Hopp (Hopp, David I, "Three topics integral to the use of the Internet for clinical trials: Connectivity, communication, and security," Drug Information Journal, Oct-Dec, 1999.) as applied to claims 24 and 25 and further in view of Brin (Brin, Dinah, "Lilly warns Nutri System about using Prozac," The Patriot Ledger, September 17, 1997, pages 5-6).

As per claims 26 and 27, the combined system of Colon and Hopp collectively fail to expressly teach determining the test substance's clinical efficacy comprises comparing the compiled data from participants using the test substance with data compiled from information from received and completed evaluation forms returned to at least one investigator by participants using a placebo. However, this feature is old and well known in the art, as evidenced by Brin's teachings with regards to this limitation. In particular, Brin teaches a clinical trial that compares test results to a control group taking placebos (Brin; page 2, paragraph 2). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Colon and Hopp with Brin's teaching with regards to this limitation, with the motivation of evaluating the effects of the test substance following standard clinical trial test procedures (Brin; page 2, paragraph 2).

Response to Amendment

6. The declaration under 37 CFR 1.131 filed on 12/30/2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Hopp reference.

While certain submitted documents (e.g.Exhibit A, G, I-L) establish conception of claimed invention, Applicants has failed to provide specific evidence that he worked diligently from conception until an actual reduction to practice date, or that he worked diligently from a conception until prior to October 1998 (the critical date for the Hopp reference. MPEP § 2138.06 states the following:

> An applicant must account for the entire period during which diligence is required. *Gould v. Schawlow*, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (Merely stating that there were no weeks or months that the invention was not worked on is not enough.); *In re Harry*, 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964)(statement that the subject matter "was diligently reduced to practice" is not a showing but a mere pleading). A 2-day period lacking activity has been held to be fatal. In re Mulder, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR 1.131 issue); Fitzgerald v. Arbib, 268 F.2d 763, 766, 122 USPQ 530, 532 (CCPA 1959) (Less than 1 month of inactivity during critical period. Efforts to exploit an invention commercially do not constitute diligence in reducing it to practice. An actual reduction to practice in the case of a design for a three-dimensional article requires that it should be embodied in some structure other than a mere drawing.); Kendall v. Searles, 173 F.2d 986, 993, 81 USPQ 363, 369 (CCPA 1949) *(Diligence requires that applicants must be specific as to dates and facts.)* *(Emphasis added)*

The Applicant also provides a statement declaring that he worked diligently in developing the invention with no time lapses occurring. The Applicant evidence submitted by the Applicant does not account for any of the time lapses during the 2 month time period of August 14-Oct. 19, 1998. The applicant has also submitted a series of invoices dated 12/7/98-3/9/1999. These documents also include a plurality of time lapses, and it is unclear to the Examiner how these documents are intended to support the declaration. As such, it is submitted that the Applicant has failed to provide

evidence to fully account for the time period during which due diligence must be established.

Response to Arguments

7. Applicant's arguments with respect to amended claims 1-14,16-18, and 20-38 have been fully considered but they are not persuasive.

(A) At pages 4-6 of the 4/30/04 communication, Applicant argues each of the applied references individually.

In response, the Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Colon has been relied upon to disclose the overall method and structure of a clinical trials system, which assigns unique ID's to its uses to provide secure access.

Hopp teaches the use of the Internet for clinical trials and teaches documents, such as contracts, informed consent forms, and study procedure manuals, shared with clinical trial participants for viewing and printing (Hopp; page 4, paragraphs 1-2; "instruction on using the test substance" i.e. "study procedure manuals.") Furthermore, Hopp also teaches that a clinical trial participant's access to the system is confidential and controlled. It is the combination of references, which has been relied upon to address the limitations of claim 1.

As to applicant's assertion that there is no motivation to combine the references and that Colon does not suggest password protection, the goal of the Colon system is to ensure that only authorized users may access the appropriate information (col. 2, lines 21-23). Morever, the motivation to combine the two references was provided from the secondary reference.

The arguments regarding claims 26-27 are also addressed by the arguments regarding claim 1, and are incorporated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is 571-272-6775. The examiner can normally be reached on Monday through Friday, 9:30 A.M. to 6:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RP

ALEXANDER KALINOWSKI
SUPERVISORY PATENT EXAMINER